DEPARTMENT OF HEALTH AND HUMAN SERVICES

RB 1/10/01 5053

Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

January 9, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
KAN #2001-03

Mr. Norman E. Rose, Owner
The Hormone Shop, LCC
7128 Cedar
Prairie Village, Kansas 66208

Dear Mr. Rose:

This letter is written in reference to your marketing of the products, Progest-E Complex Replenishing Oil, Melatonin Capsules, Pregnenolone Capsules, and 5-HTP Capsules. Your Internet web site promotes these products as useful in the treatment of various diseases. For example, your site makes statements indicating that each of the products listed above are effective in treating the following conditions:

Progest-E Complex: migraines, arthritis, bursitis, asthma, diabetic vascular problems, endometriosis, epilepsy, glaucoma, goiter, infertility, porphyria, stroke.

Melatonin: cancer fighter, potential AIDS therapy.

Pregnenolone: Alzheimer's disease, depression, rheumatoid arthritis.

5-HTP: depression, panic disorder, migraines, behavioral disorders.

Because your Internet web site includes statements which represent or suggest that these products are intended to be used in the cure, mitigation, treatment, or prevention of disease, these products are drugs under Section 201(g) of the Act. We are unaware of any evidence which establishes that these drugs are generally recognized as safe and effective for their intended uses. Therefore, these products are also new drugs as described in Section 201(p) of the Act which may not be legally marketed in the United States since no new drug application has been approved for any of these drugs as required by Section 505 of the Act.

These drugs are also misbranded under Section 502(a) of the Act because their labeling is false or misleading. Your web site suggests that there is evidence that these drugs are safe and

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effective for their intended uses, but, in fact, this has not been established. These drugs are further misbranded under Section 502(f)(1) of the Act because their labeling fails to bear adequate directions for all of their intended uses as further described under Title 21, Code of Federal Regulations, Section 201.5(a) [21 CFR § 201.5].

We request that you notify this office in writing within 15 working days of receipt of this letter stating the action you will take to discontinue the marketing of these drug products or to otherwise bring them into compliance. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. The Act provides for seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

This letter does not represent a comprehensive review of all of the products distributed by your firm. It also does not represent a complete review of your Internet web site nor any other product labeling or promotional materials you may use. As the owner, it is your responsibility to ensure that all products distributed by your firm meet the requirements of the Act and its implementing regulations.

Your reply should be directed to Monica R. Maxwell, Compliance Officer, at the address on the letterhead.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District